K112713

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Norfolk Medical

7350 N. Ridgeway, Skokie, IL 60076 • 847-674-7075

510(k) Summary Table 1

OCT 27 2011

Date:	September 16, 2011
Submitter:	Norfolk Medical Products Inc. 7350 N. Ridgeway Skokie, IL 60076
Contact Person:	Michael J. Dalton President Norfolk Medical Inc 847-674-7075 847-674-7066 (fax) mjdalton@norfolkmedical.com
Device:	
Trade Name:	SportPort™
Common/Usual Name:	Port and catheter, implanted, subcutaneous, intravascular
Classification Names:	
CFR Reference:	21CFR 880.5965
Classification Name:	Port and catheter, implanted, subcutaneous, intravascular
Product Code:	LJT
Predicate Devices:	NorPort CT-PC Port - 510(k) # K111101

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2.1 Device Description

The devices are to be used by or on the order of a physician. The SportPort™ line of ports has a body/septum retainer made of either commercially pure grade 2 titanium or medical grade MG-11 polysulfone chamber with a silicone rubber septum designed for repeated needle puncturing. The SportPort™ comes in a standard design to enable regular use as an infusion/withdrawal port and has high-pressure injection capability to aid to the delivery of large volumes of specialty fluids such as contrast media. The shape of the base plate of the port body is triangular and is compatible with most imaging systems. The top of the port (septum retainer) has an elongated cut out surrounding the septum to secure the septum in place during high-pressure use and to enable palpable or image system identification. The port has six (6) elongated holes for suture fixation to the deep fascia tissue during implantation. The fixation is required to prevent migration or flipping of the port. A catheter comes with the port and is inserted into the vascular system. The catheter is usually inserted into a venous vessel and fed down into the vascular system. The catheter is radiopaque to enable visualization for proper placement. The kit provided to aid in insertion of the catheter and placement of the port may include items like needles, sheaths, vein picks, guidewires, straighteners, and dilators. Likewise, the cut down kit for port placement may contain tunnelers, infusion sets with Lucent Non-Coring needles, straight pointed Huber needles, blunt needles, and syringes along with the port and catheter.

The Norfolk Medical SportPort™ family of ports provides a simple method for the delivery of volumes of medications, fluids and special fluids like chemotherapy agents via a chamber leading to a catheter and opening into a large vessel in the body. The catheter is inserted into a large vessel that ideally terminates in the superior vena cava/high right atrial junction. The port is surgically implanted subcutaneously in the soft tissue near the clavicle on the patient's right upper chest wall. Medications, fluids, nutritional liquids or chemotherapy agents can then be administered as necessary. The ports are intended for long-term placement.

The Norfolk Medical SportPort™ family of Vascular Access Devices is a group of ports and catheter sets with infusion and withdrawal capabilities via a port and an access catheter to the large vessels in the vascular system. These ports must be properly attached to a catheter during a procedure

When used with a legally marketed power capable needle infusion set, the SportPort™ is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/sec with a 19 or 20 gauge needle and 2ml/sec with a 22 gauge needle set.

2.2 Intended Use

The intended use and precautions and complications to be considered prior to the use of the Port are contained in the Instructions For Use / User's Manual attached as Exhibit A. The SportPort™ is indicated for use when the patient requires the following - repeated access to the vascular system for injections, infusion drugs, administration of blood or blood products, and/or withdrawal of blood as part of the therapy regimen.

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When used with a legally marketed power injectable needle infusion set, the SportPort™ is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s with a 19 and 20 gauge non-coring power injectable needle and 2 ml/s with a 22-gauge non-coring power injectable needle.

2.3 Technology

The SportPort™ does not alter the fundamental scientific technology of the predicate device.

2.4 Conclusion

The results of these measurements demonstrated that the SportPort™ is as safe, as effective, and performs as well as the predicate device.

The indications for use statements for the SportPort™ and all substantially equivalent devices are similar. All the products have similar target populations as described in their intended use statements. All of them target a population of patients who must have repeated access to their vascular system for the delivery of medications, I.V. fluids, special fluids such as contrast media, or nutritional substances and blood products or withdrawal of blood.

The SportPort™ and the predicate product are similar in design. All the materials are similar in the titanium and polysulfone products. The SportPort™ and the predicate devices have "power injectable" capabilities and they have been engineered to withstand high internal pressures in the chamber and through the catheter, catheter securing mechanism, and port outlet for certain "pressure injectable" clinical applications.

All the products are intended for use as sterile, single use products. The SportPort™and the NorPort product line of ports have the same biocompatible materials in their construction. They are made from the same materials, utilizing the same manufacturing process.

The SportPort™ has been mechanically tested for leaks, septum puncturing, catheter tensile strength testing, catheter to port connection test, dynamic failure testing, patency verification testing, and static burst testing.

There are no chemical safety issues, no energy use/energy generation issues, nor any environmental compatibility issues with the SportPort™. There are no electrical, thermal, or radiation safety issues with this port.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 27 2011

Mr. Michael J. Dalton
President
Norfolk Medical Products, Incorporated
7350 North Ridgeway
Skokie, Illinois 60076

Re: K112713
Trade/Device Name: SportPort™
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: September 16, 2011
Received: September 28, 2011

Dear Mr. Dalton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): Unknown at the present time

Device Name: SportPort™

Indications For Use:

The SportPort™ is indicated for use when the patient requires the following: repeated access to the vascular system for injections, infusion of drugs, administration of blood or blood products, and/or withdrawal of blood as part of the therapy regimen.

When used with a power injectable needle infusion set, the SportPort™ is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s with a 19 or 20 gauge non-coring power injectable needle and 2 ml/s with a 22-gauge non-coring power injectable needle.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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